

K092857

MAR - 4 2010

VII. Section 10 - 510(K) Summary

This summary of 510(K) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92

1. Applicant's Name and Address

Whip Mix Corporation,
Lab Services Division
361 Farmington Ave.
Louisville, Kentucky 40217
Telephone Number: 502-634-1451
Fax Number: 502-634-4512
Contact Person: Frederick T. Kapp
Quality Manager

2. Name of Device

Trade Name: **Vericore Custom Abutment in Titanium** - for Implant Systems: NobelBiocare, Southern Hexed, Zimmer, 3i, 3i Certain, Straumann, Nobel Replace, Southern Trilobe, Astra, and Endospore.

Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.360
Product code: NHA

3. Legally Marketed Device to which Equivalence is claimed(Predicate Device)
Vericore Abutments in Zirconia (K090976 and K082299)

4. Description of Device

The Devices covered in this submission are abutments which are placed on the dental implant to provide support for a prosthetic restoration.

Vericore Abutments are made from Titanium grade Ti-6Al-4V. The abutment screws and are made from Titanium grade Ti-6A1-4V. The abutment is made to be placed over the implant and is mounted on to the implant with an abutment screw. The abutments are compatible with the following implant systems:

Zimmer – Narrow, Regular, Wide
Nobel Biocare – Narrow, Regular, Wide
3i – Regular Hexed
3i Certain – Narrow, Regular, Wide
Southern Hexed – Narrow, Regular, Wide
Endospore – Narrow, Regular and 5mm
Nobel Replace- Narrow, Regular, Wide and 6mm
Southern Trilock – Narrow, Regular and Wide
Astra – Narrow and Regular
Straumann – Narrow, Regular and Wide

5. Indications for Use

The Vericore Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The abutment is placed over the implant and is mounted on to the implant with an abutment screw.

This device is compatible with the following manufacturers' implant systems: Nobel Biocare, Southern Hexed, 3i, 3i Certain, Zimmer, Endopore, Nobel Replace, Southern Trilobe, Astra and Straumann.

This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Angled abutments and narrow diameter implants are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

List a

Zimmer – Narrow, Regular, Wide

Nobel Biocare – Narrow, Regular, Wide

3i – Regular Hexed

3i Certain – Narrow, Regular, Wide

Southern Hexed – Narrow, Regular, Wide

Endopore – Narrow, Regular and 5mm

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Southern Trilock – Narrow, Regular and Wide

Astra – Narrow and Regular

Straumann – Narrow, Regular and Wide

6. Non-clinical Testing Data

Fatigue Testing

Fatigue testing was conducted according to ISO 14801 Dentistry – Implants – Dynamic fatigue test for endosseous dental implants with the worst case scenario for each connection platform style for the Vericore Custom Abutment in Titanium and an angled abutment. The resulting information demonstrated a substantial equivalence of both the fatigue failure load and fatigue failure mode to predicate devices.

Dimensional Analysis

Dimensional analysis was conducted on the implant and abutment interfaces in order to determine the dimensions for the Vericore Custom Abutments in Titanium.

7. Basis for Substantial Equivalence

Vericore abutments are substantially equivalent to Vericore Zirconia Abutments for (K090976). Both devices are abutments made for the implant systems named above. The interface designs are the same, the same dimensional analysis was done and the fatigue testing showed substantial equivalence. The indications for use for the 2 Vericore systems is the same. The submitted abutments of Titanium are substantially equivalent to the abutments made in Zirconia.

Date the Summary Was Prepared: March 2, 2010



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Frederick T. Kapp
Quality Manager
Whip Mix Corporation
Lab Services Division
361 Farmington Avenue
Louisville, Kentucky 40217

MAR - 4 2010

Re: K092857

Trade/Device Name: Vericore Custom Abutment in Titanium – for Implant Systems:
NobelBiocare, Southern Hexed, Zimmer, 3i, 3i Certain,
Straumann, Nobel Replace, Southern Trilobe, Astra, and
Endospore (see attached list a)

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II

Product Code: NHA

Dated: February 18, 2010

Received: February 19, 2010

Dear Mr. Kapp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Vericore Custom Abutment in Titanium - for Implant Systems:
NobelBiocare, Southern Hexed, Zimmer, 3i, 3i Certain, Straumann, Nobel Replace,
Southern Trilobe, Astra, and Endospore (see attached list a)

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Prescription Use AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF
NEEDED)

ASBetz DDS for Dr. K.P. Mulley
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092857